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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,773	11/28/2001	Yoshinobu Hanyu	P21651	9572

7055 7590 09/20/2005

GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/994,773

Applicant(s)

HANYU ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-15 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-15 and 20-24 is/are rejected.
- 7) ☒ Claim(s) 6-7 and 18-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The applicant's response filed 3/14/2005 to the Office action mailed 12/15/2004 has been entered. Claims 1-3, 6-15 and 18-24 are pending.

1. The objection of claims 1-3 and 6-12 are withdrawn because of the amendment.
2. Claims 1-3 and 6-12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-3 and 4-12 are vague and indefinite because the preamble is for preparing a powder containing the physiologically active peptide, but there is no an active step for preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiological active peptide. Clarification is required.

Although the claims are amended, there is still no an active step for preparing a powder containing the physiologically active peptide by drying an aqueous liquid containing the physiological active peptide.

3. Claims 1-3, 8-15, and 20-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrand et al. (6103,697, issued August 15, 2000) further in view of Oyama et al. (6,117,434, issued September 12, 2000).

Bergstrand et al. disclose the preparation of pharmaceutical preparation containing a peptide (See column 12, lines 56-57). The active peptide may be admixed with mannitol, or cellulose derivatives or polyvinylpyrrolidone (See column 12, lines 56-67) and surfactants lecithin (see column 13, lines 53-55). A solution containing active peptide was dried by lyophilization (See example 34, column 9, lines 58-60). The physiologically active peptide is

Art Unit: 1637

human growth hormone (See column 2, lines 15-20). The size of a particle is suitable for inhalation (mass median diameter less than 4  $\mu\text{m}$ ) (See column 13, lines 41-43).

Bergstrand et al. do not disclose the amount of a nonionic surfactant, a nonionic, organic, water-soluble binder and mannitol used in the method.

However, it would have been prima facie obvious to select the specific ratio of weight of these compounds used in the method for preparing a powder for containing a physiological active peptide, because the selection of the amount of these compounds used in the method represents routine optimization with regard to sequence, length and the amount of the compounds used in the method for preparing a powder containing a physiological active peptide.

Routine optimization is not considered inventive and no evidence has been presented that the weight ratio used in the method for preparing a powder containing a physiological active peptide was other than routine, that the method resulting from the optimization have any unexpected results or the results should be considered unexpected as compared to the closest prior art.

Bergstrand et al. also do not disclose using hydrogenated lecithin.

Oyama et al. disclose using hydrogenated lecithin in a moisturizing composition in view of oxidation stability (See column 2, lines 32-33).

One of ordinary skill in the art at time of the invention would have been motivated to add hydrogenated lecithin in an aqueous solution containing active peptide because of the oxidation stability of hydrogenated lecithin as taught by Oyama et al.. It would have been prima facie obvious to use hydrogenated lecithin in an aqueous solution containing active peptide in a process of preparing a powder.

The response states that the reference of Bergstrand does not disclose the instant invention, for example, the method of Bergstrand is to prepare peptides having immune effect, which is not growth hormone, and the lyophilization step is used in the first step of the peptide purification. However, the limitation regarding the type of the peptide is not in claims 1 and 13. In addition, the teachings of lyophilization step are to indicate that there is a way to make powder from an aqueous phase. Moreover, there is not an order in the instant method steps and the phrase "comprising" is used to describe the method steps. So any steps can be added to fulfill the method.

The response further argues that there is no teaching that surfactants or other additives are added to physiologically active peptide in aqueous solution to stabilize a physiologically active peptide during drying and then dried to form powder and Oyama et al. use hydrogenated lecithin in a moisturizing composition in view of oxidation stability (See column 2, lines 24-34). However, the moisturizing composition can contain water (See column 2, lines 24-25). Therefore one of ordinary skill in the art at time of the invention would have been motivated to add hydrogenated lecithin in an aqueous solution containing active peptide because of the oxidation stability of hydrogenated lecithin as taught by Oyama et al.. Although the instant invention is to prepare a powder containing a physiologically active peptide, the hydrogenated lecithin is added to the aqueous solution and then the solution is dried. With the benefit of using hydrogenated lecithin in a moisture lotion as taught by Oyama et al., it would have been prima facie obvious to use hydrogenated lecithin in an aqueous solution containing active peptide in a process of preparing a powder.

***Allowable Subject Matter***

4. Claims 6-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 6-7, 18 and 19, no prior art has been found teaching or suggesting applying the water-soluble, nonionic cellulose derivative selected from the group of hydroxypropylcellulose, hydroxyethylcellulose and hydroxypropylmethylcellulose or the nonionic surfactant selected from the group of polysorbate, polyoxyethylenehydrogenated castor oil and a poloxamer to an aqueous liquid in a process of preparing a powder containing the physiologically active peptide.

**Summary**

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1637

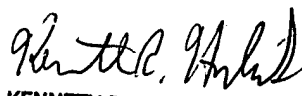
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung  
September 14, 2005

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

9/14/05